REMARKS

In addition to the changes in the claim language that are discussed below, editorial changes have been made in a number of claims to correct the dependency, and the method claims have been editorially amended to use language that is more appropriate for claiming method steps. All of these changes are supported in the specification as originally filed, and no new matter is added thereby.

Claims 27-33, 33-38, 41-43, 47-54, 57-59,.62 and 63 were provisionally rejected on the basis of non-statutory double patenting over claims 21, 22, 26-29, 31, 34, 35, 38-40 and 42 of co-pending Application Serial No. 10/562,109.

This double patenting rejection is respectfully traversed for the following reasons.

First, in substantiating a non-statutory obviousness-type double patenting rejection, it is important to remember that it is the claim language, and only the claim language, that is relevant for comparison purposes. The *disclosure* of the patent that is used as the basis for obviousness-type double patenting cannot be relied upon in any manner for "interpreting" the claims of the patent that forms the basis for the rejection.

The Federal Circuit has stated many times that the basic issue involved in an obviousness-type double patenting rejection is whether any claim of the application in question defines merely an obvious variation of an invention in a co-pending application or patent, and in doing so the disclosure of the co-pending application or patent cannot be used as prior art. *In re Kaplan*, 789 F.2d 1574, 1579 (Fed. Cir. 1986). As stated in *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC,* 349 F.3d , 1373, 1385 (Fed. Cir. 2003):

> Because non-statutory double patenting compares earlier and later claims, an earlier patent's disclosure is not available to show non-statutory double patenting.

Consistently, in *Ortho Pharmaceutical Corp. v. Smith*, 959 F.2d 936, 943 (Fed. Cir. 1992), the Federal Circuit stated:

> It is the claims, not the specification, that define an invention... . And it is the claims that are compared when assessing double patenting.

In General Foods Corp. v. Studiengesellschat Köhle mbH, 972 F.2d 1272 (Fed. Cir. 1992), the Federal Circuit stated:

> [C]omparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claimed *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference... .Our precedent makes clear that the *disclosure* of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, *even where the disclosure is found in the claims.* (emphases in original)

This being the case, there are a number of explicit and significant differences in the claim language in the cited claims of the present application, and the cited claims of the co-pending application. First and foremost, all of the claims in the present application refer to the DHF parameter as being related to a *time duration* of a predetermined phase of diastole of the heart. There is no mention of any type of time duration measurement of any sort in the cited claims of the co-pending application.

Moreover, the claims of the co-pending application each explicitly refer to measurement of the *magnitude* of pulse pressure, and there is no mention whatsoever of any mention of *magnitude* of any parameter in the claims of the present application.

There is no basis in the language of the claims themselves to equate these two differently-described measurements as being equivalent to each other, or one being a more generic form of the other so that granting of a patent claim with regard to one of those limitations would somehow be an extension of a patent grant with regard to the claims of the other application.

As such, Applicants disagree with the Examiner's statement that " the subject matter claimed in the instant application is fully disclosed in the referenced pending application and would be covered by any patent granted on that co-pending application. In substantiation of this statement, the Examiner simply stated that both inventions are directed toward pressure detection of diastolic heart failure. In view of the above decisions, however, this is clearly an insufficient basis for substantiating a double patenting rejection . The above decisions also make clear that the Examiner is erroneous as a matter of law by referring to the subject matter in the present application being "fully disclosed in the referenced co-pending application." As noted above, it is impermissible to use the *disclosure* of a co-pending application as a basis for substantiating a double patenting rejection. The claim language, and only the claim language, of the present application must be compared with the claim language, and only the claim language, of co-pending Application Serial No. 10/562,109. For the above reasons, when the proper comparison of the claim language is made, a situation involving double patenting clearly does not exist.

Additionally, claims 27-33, 36-38, 41-43, 47-54, 57-59, 62 and 63 were rejected under 35 U.S.C. §102(e) as being anticipated by Baumann et al. This rejection is respectfully traversed for the following reasons.

The implantable medical apparatus, cardiac pacemaker and method disclosed and claimed in the present application are for the purpose of providing an early status indication of diastolic heart failure (DHF). As summarized in the introductory portion of the present specification, and as explained in several of the references cited in the Information Disclosure Statement filed December 22, 2005, DHF is not the same as congestive heart failure (CHF), and is more difficult to detect or predict. In the subject matter disclosed and claimed in the present application, an indicator of the DHF status of the heart of a subject is generated by determining a time duration of a predetermined phase of diastole of the heart. This time duration is used as a parameter that is indicative of DHF, and, in the amended claims, an output signal is generated that embodies this parameter as a DHF indicator. In other words, the ultimate result of the apparatus, pacemaker and method disclosed and claimed in the present application is the emission of a signal that indicates DHF (if present).

The Baumann et al. reference does not disclose any specific techniques for identifying or detecting DHF, and merely provides a general assessment of the hemodynamic operation of the heart of a subject, so as to optimize lead placement for the subject. As stated in the paragraph beginning at column 1, line 17, the purpose of the optimized lead placement in the Baumann et al. reference is for the purpose of improving the hemodynamics in congestive heart failure patients, but there is no teaching or disclosure in the Baumann et al. reference regarding how to detect or identify CHF in the first place. It is simply assumed in the Baumann et al. reference that the lead optimization procedure disclosed therein will be applied to a patient who is exhibit CHF, and then an optimized lead placement configuration can be identified as being the configuration that produces the most favorable measured

hemodynamics. Therefore, even in the context of CHF, there is no detection algorithm disclosed or suggested in the Baumann et al. reference. The Baumann et al. reference is therefore even farther removed from disclosing any sort of detection procedure or device for DHF.

Applicant acknowledges that, as an alternative to using a pressure sensor (which the Baumann et al. reference discredits), the Baumann et al. reference makes a measurement that is used as an indirect indicator of pulse pressure, namely a measurement of the patient's atrial cycle length (ACL), as explained at column 1, lines 30-32.

In the Baumann et al. reference, however, because ACL is being used as an indicator for pulse pressure, Baumann et al. are concerned only in detecting a change in the ACL, because it is known that this change in ACL has a physiological correlation to a *change* in the pulse pressure. Since Baumann et al. are concerned with identifying a *change* in ACL, it would not be possible, for the intended purpose disclosed in Baumann et al., to obtain any useful information from making a measurement of only a single ACL duration, as is possible in the subject matter of the present application. In the present application, the actual duration of ACL, by itself, is used as a DHF-indicating parameter. There is no teaching in the Baumann et al. reference that measuring ACL has any such benefit. As noted above, the claims of the present application have been amended to make clear that, as a result of measuring the aforementioned time duration of a predetermined phase of diastole of the heart, a signal is emitted that is used as an indicator of the DHF status of the patient. Simply making a measurement of ACL, or more specifically a *change* in

ACL, a disclosed in Baumann et al., does not resolve in the emission of such a DHF indicator signal.

Therefore, the Baumann et al. reference does not disclose all of the elements of claims 27-33, 36-38, 41-43, 47-54, 57-59, 62 or 63, and thus does not anticipate any of those claims.

Claims 34, 35, 39, 40, 55, 56, 60 and 61 were rejected under 35 U.S.C. §103(a) as being unpatentable over Baumann et al. in view of Salo et al., and claims 44 and 45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Baumann et al. in view of Paul et al.

The above discussion concerning the Baumann et al. reference is equally applicable to these rejections, which are traversed on the same basis. Even if the Examiner is correct regarding the teachings of the Salo et al. and Paul et al. references, modifying the Baumann et al. reference in accordance with those teachings still would not result in the subject matter of any of the aforementioned claims, in view of the above-discussed deficiencies of the disclosure in Baumann et al.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

(Reg. 28,982)

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